

REMARKS

Claims 20, 22-24 and 26-43 are pending in the present application. Claims 20, 32 and 41 are amended. New claim 44 is added. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Accordingly, claims 20, 22-24 and 26-43 are currently under consideration.

Entry of the amendments and reconsideration of the application is respectfully requested in view of the above amendments and the following remarks.

A. Claim Amendments

Claims 20, 32 and 41 are amended to specify that the "therapeutic agent is a substantially non-denatured protein, peptide or enzyme produced by a process which is controlled to avoid denaturing of the protein, peptide or enzyme." (emphasis added)¹. Basis for the limitation "produced by a process which is controlled to avoid denaturing of the protein, peptide or enzyme" is found in the Specification at page 6, lines 23-37, and 35 and page 7, lines 3-7, Examples 1 and 2 at pages 22-23 disclosing spray-drying procedures that lead to "little or no structural damage to the protein (*see* page 23, lines 6-8 and 16-24. No new matter has been added. Entry of the amendment is respectfully requested.

New claim 44 is added. Claim 44 incorporates the "phospholipid" limitation of pending claim 34 into the language of claim 20. No new matter is added.

B. Rejections under 35 USC § 103

Claims 20, 22-24 and 26-43 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over Platz et al. (US 6,509,006).

¹ Claim 32 recites "a substantially non-denatured protein selected from the group consisting of insulin, parathyroid hormone, alpha-1 antitrypsin and calcitonin produced by a process which is controlled to avoid denaturing of the protein."

While Platz (US Pat. No. 6,509,006) itself is not prior art against the present application, the Examiner maintains that the earliest priority document that Platz is entitled to, Ser. No. 07/910,048 (U.S. Pat. No. 5,458,135; "the '135 patent") discloses relevant material.

The Examiner acknowledges that substantially non-denatured proteins, peptides or enzymes are not explicitly taught by Platz. However, the Examiner states that the disclosure of Platz is broad enough to encompass all types of proteins including non-denatured proteins, peptides or enzymes, as recited in claim 20.

In the previous response to the non-Final Office Action, Applicants argued that none of the Platz et al. references teach that spray-drying conditions are controlled to minimize denaturation. The Examiner finds that such a difference is not recited in the claims.

In response, Applicants amend claims 20, 32 and 41 to specify that the substantially non-denatured protein, peptide or enzyme is "produced by a process which is controlled to avoid denaturing of the protein, peptide or enzyme." New claim 44 also incorporates this limitation. Applicants submit that none of the Platz et al. references teach any method to control spray-drying conditions to avoid denaturation.

Each and every limitation of independent claims 20, 32 and 41, as amended, and new claim 44, is not taught by the prior art. Therefore, Applicants submit that a prima facie case for obviousness cannot be made. Claims 22-24 and 26-43 depend from claims 20, 32 and 41. Therefore, Applicants respectfully request withdrawal of this ground for rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to ***Deposit Account No. 03-1952*** referencing docket no. **263742002802**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

Electronic signature: /Shantanu Basu/
Shantanu Basu
Registration No.: 43,318

MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-5995